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Author/s:

Leask, J;Danchin, M

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Title page

Imposing penalties for vaccine rejection requires strong scrutiny.

Viewpoint

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Julie Leask MPH, PhD

Associate Professor

Sydney School of Public Health, University of Sydney

julie.leask@sydney.edu.au

Ph +61 2 93515307

Margie Danchin MBBS PhD

Senior Research Fellow, Vaccine and Immunisation Research Group

Murdoch Children's Research Institutes

Royal Children's Hospital, Melbourne VIC AUSTRALIA

Margie.Danchin@rch.org.au

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Abstract

Vaccine rejection presents a persistent challenge for clinicians and policy makers. In response, some countries are penalising parents who actively reject vaccination for their children. The Australian government introduced the “No Jab No Pay” amendment bill in 2015 which removed vaccine objection exemptions so that parents who actively rejected some or all vaccines were no longer able to obtain family assistance payments.

We consider this approach with Verweij and Dawson’s seven ethical principles for public health immunisation programs which relate to benefits and risks, effectiveness, equity and justice, autonomy, reciprocity, and trust. Despite some marginal gains from the removal of objection exemptions, there are significant social and economic risks for the most vulnerable. The penalties are applied differentially through income testing, causing lower income vaccine objectors to be more affected than those on a higher income. They also compound the disadvantage for children already at greater risk of vaccine-preventable diseases and they create more alienation from a healthcare system that vaccine rejecting and hesitant parents already struggle to trust. Furthermore, the No Jab, No Pay amendment bill has been implemented without a no-fault vaccine injury compensation system, in acknowledgement of the risks of rare, serious side effects of vaccination. Such policies should be evaluated with these and other unintended negative consequences in mind.

An evidence-based approach to under-vaccination requires multifactorial approaches that ensure the inadvertently under-vaccinated are reminded and supported to fully vaccinate their children whilst active rejectors of vaccination are able to access services and financial assistance through exemptions that are difficult to obtain. There is also a need for stronger evidence on ways to address vaccine hesitancy and rejection.

Background

At a time when vaccine-preventable diseases are better controlled than ever, vaccine rejection presents a persistent challenge for clinicians and policy makers. Efforts to address vaccine rejection often fail because its under-pinning is complex and the traditional top-down models that enable efficient delivery of vaccines to children are not as effective with hesitant or rejecting parents. Whilst there is evidence to support strategies to improve vaccination coverage more broadly,^{1,2} there is a very limited evidence base to address vaccine rejection.³ Rejection of vaccines is only one contributor to under-vaccination, with inadvertent lateness or missed opportunities due to access issues being the larger contributor to under-vaccination in Australia.⁴ However, the mainstream media tend to frame the cause as solely resting with 'anti-vaxxers',^{5,6} leaving the public to assume that the solution should focus on any policy that predominantly targets vaccine rejection.

Australia and other countries have considered or implemented policies that ramp-up the penalties for rejection of vaccination. In the United States, California recently passed legislation, joining Mississippi and West Virginia, in eliminating all but medical exemptions for school entry.⁷ The American Academy of Pediatrics (AAP) released a policy statement in August to support the

elimination of all non-medical exemptions and have given more explicit support to paediatricians who wish to dismiss vaccine rejecting parents from their practice.^{8,9} By contrast, the Royal Australasian College of Physicians do not support the removal of non-medical exemptions and explicitly discourage dismissing unvaccinated children from the practice.¹⁰

However, the Australian government has removed non-medical exemptions, previously in place for parents who actively declined vaccination for their children. On November 23 2015, the federal government passed The Social Services Legislation Amendment (No Jab, No Pay) Bill 2015. The amendment's centrepiece was the removal of the vaccination "conscientious objection" exemption to immunisation requirements which had been linked to receipt of Family Assistance Payments since 1999. By 2015, these payments included Family Tax Benefit (FTB) part A (supplement), the Child Care Rebate and Child Care Benefit which together could amount to approximately \$15,000 each year for those on the lowest incomes. As of 2016, the only exemptions to the requirements are: a medical contraindication, natural immunity to a disease, being in a vaccine study, temporary unavailability of vaccine, child vaccinated overseas, or a decision at the discretion of the Secretary.

Meanwhile, three state governments have introduced 'No Jab No Play' legislation introducing or tightening requirements for enrolment into child care and pre-school. The most stringent legislation is in Victoria which completely excludes children from early childhood services when they are not fully vaccinated and are without a medical exemption.¹¹ Queensland has given child care providers discretionary power to exclude such children.¹² New South Wales has not instituted a full removal of conscientious objection exemptions for enrolment in child care, but instead have tightened existing documentation requirements.¹³

The policies were explained as intending to increase vaccination rates and mitigate the risk of VPDS to the Australian community.¹⁴ Hence, understanding the evidence base and effectiveness of penalties to address vaccine rejection is vital, as Australia evaluates “No Jab No Pay” and as other countries consider implementing similar measures.

Below we outline the issues for consideration via the Seven Ethical Principles for public health immunisation programs outlined by Verweij and Dawson and elaborated by Isaacs.^{15, 16} We relate them to the “No Jab No Pay” policy specifically where the penalty for vaccine rejection is financial, but a downstream effect can result in child care becoming unaffordable for those affected by the removal of the Child Care Benefit and Rebate. The article does not focus on impacts from state-based ‘No Jab No Play’ policies which focuses on refusing enrolment in child care or pre-school facilities for under or non-vaccinated children. However, there is significant overlap to the extent that the end result is reduced access to childcare.

Benefits:

Potential to increase immunisation rates

Australia has set an aspirational coverage target of 95% for children.¹⁷ A slight rise in immunisation rates has occurred in the six months since the No Jab No Pay bill’s introduction. The 12 months of age milestone saw vaccination rates go from 92.28% to 93.22% by September 2016 – representing a rise of 0.94%.

Regarding objectors, 5,738 children whose parents were receiving child care payments and who were previously registered as vaccination objectors, had had their children vaccinated since the launch of the policy.¹⁸ Assuming this pertains to children aged under 6 years, it is 19% of all objectors registered in December 2015 and 0.26% of all children aged under 6 years. The remaining 24,354

children or 81% of all registered vaccine objectors either do not qualify (were not receiving payments) or are yet to comply with requirements.

Reduced risk of exposure to incompletely-vaccinated children in child care

The “No Jab, No Pay” policy has reduced affordability of child care for some families who previously accessed the Child Care Benefit and Rebate. By limiting incompletely vaccinated children from accessing child care, a reduced spread of VPDs in the child care setting is possible, providing additional protection to those who are immuno-compromised or too young to be vaccinated. It is not clear whether a subsequent potential of clustering of the unvaccinated in informal child care arrangements will counteract these benefits by providing new reservoirs.

Increased knowledge and awareness about the importance of immunisation

The legislation attracted considerable publicity in all major media and online outlets at three major time points: when it was announced on 12 April 2015, passed in November and implemented from 1 January 2016. Headlining news saw multiple media messages that affirmed the importance of vaccination. Some states ran specific campaigns to strengthen the immunisation message alongside the announcement of their policy, such as Victoria’s “Immunity for Community” campaign. This intensified focus highlighted the existing and new requirements and more broadly the overall importance of immunisation.

Savings for government

The 2015 federal budget predicted savings of \$508.3 million from the “No Jab, No Pay” policy over the forward estimates.¹⁹ Some of this money may have been put into immunisation programs: a week following the announcement of the “No Jab

No Pay” policy by the Prime Minister and Minister for Social Services, the Minister for Health announced an additional \$26 million for vaccination programs.²⁰

Risks

Imposing penalties on vaccine rejectors does not target the largest contributor to under-vaccination

The bill was aimed at those who registered a vaccine objection, which hit a peak of 1.8% in 2015. However, with vaccination rates at 92.0%, there was a remaining 6.2% who were not up-to-date on ACIR and not accounted for by objection. They represented the largest of the two under-vaccinated groups and would be unaffected by the new policy’s centrepiece – removal of the objection exemption – because they were not already lodging an exemption. They included:

1. children who were fully vaccinated but recording error has resulted in them being falsely classified as not up-to-date on the ACIR;
2. children of vaccine objectors who did not register their objection;
3. children of the vaccine-supportive who were late for a range of practical and logistical reasons related to access or disadvantage.

The first group needed assistance in addressing errors in the ACIR record. The third group needed other measures that removed logistical and financial barriers, made vaccination services easily accessible, and minimized missed opportunities. Accordingly, the Department of Health’s additional \$26 million was pledged towards a range of measures including catch-up incentives for providers, free catch-up vaccines for children under 10yrs (ongoing) and time-limited for children 7 years to 19 years (for 2 years).

Catch-up support is particularly important: for example, it has been estimated that 37% of children likely to have been born overseas were not fully vaccinated according to ACIR – a figure that does not count those affected by registered objection.⁴ Instituting complex catch-up arrangements can be difficult when previous records are incomplete or in another language, such as is the case for many migrant and refugee families.²¹ Incentivising catch-up has a greater chance of raising vaccination rates than penalties because it targets this larger, more motivated, and unintentionally not up-to-date group. Finally, the most significant benefit of the additional funding was the establishment of the Australian Immunisation Register, which extends the childhood register to the whole-of-life and commenced operation on 30 September 2016. It would enable better monitoring of adult vaccination coverage where significant under-vaccination occurs.

Evidence suggests a less restrictive option can bring larger gains

A US review examining impact of monetary penalties in raising immunisation rates found insufficient evidence to determine their impact on vaccination rates, based on the small number of studies; differences in the type of penalties evaluated; inconsistent results on vaccination rates; and limited information on potential harms of these policies.²² The weight of the evidence suggests supportive strategies are more effective, such as those that remove barriers to vaccine access.^{1, 2}

In addition, the No Jab No Pay policy was justified against a background of widespread reports of an alleged decline in vaccination rates.^{23, 24} Yet, the proportion of children being fully vaccinated for age has been stable for the 12-<15 and 24-<27month age cohorts since 2003 and had increased by 10% since 2009 in the 60-<63 month age group.

Imposing sanctions will not shift many vaccine objectors

While some vaccine objectors have chosen to vaccinate, many are on incomes that are too high to be eligible for FTB-A (supplement) and the Child Care Benefit. In fact registered objectors were approximately twice as likely to reside in the top 10% of SES postcodes compared with the bottom 10%.⁴ Others who are eligible will remain unmoved, too fearful or mistrusting of vaccines to change. The estimated savings of \$508.3 million when the policy was announced implied that government anticipated many such parents would still not vaccinate.

The Bill removes the incentive for parents to discuss their vaccine rejection decision with a health professional

To meet the requirements in place between 1999 and 2015, parents who objected to vaccination had to request a doctor or immunisation provider sign a conscientious objection form which stated that the risks and benefits were explained to them. The removal of objection requirements has meant that this encounter, which represents an opportunity to address vaccine concerns, is no longer incentivised.

The bill places pressure on providers to give unwarranted medical exemptions

Instead of seeking vaccination objection exemptions, some parents who reject vaccines are now requesting medical exemptions. Providers are being put under great pressure to sign medical exemption forms by distressed and angry parents (see case studies in Table 2). This process has the potential to introduce considerable conflict in the doctor patient relationship. Criteria for medical exemptions are informed by evidence and are only legitimate in a very small proportion of children with true contraindications. Providers who relax the

criteria upon a parent's request may be seen to legitimise a more expansive set of contraindications than the evidence would suggest.

Inability to monitor vaccine rejection rates through loss of national registration of vaccine objection

Registration of vaccination objection ended 31 December 2015, which removed the capacity to record and monitor objection to vaccination over time and the ability to identify regional variations. Without such information, local planners may not develop solutions that match the cause of the problem. For example, a region may have low vaccination rates but low objection rates meaning that an education campaign to address vaccine safety concerns is a poor match for the problem which may be limited and inconvenient services. Australia currently has no other way of monitoring vaccine sentiment at a regional level to enable local planning - only coverage is monitored.

Effectiveness

Any policy instituted to improve vaccination rates should ensure that it is the right fit for the problem and should be evaluated for effectiveness. The multiple components of the “No Jab No Pay” amendment bill will have different effects on each of three under-vaccinated groups, as outlined in Table 1. A careful evaluation should determine the impacts and outcomes of the “No Jab No Pay” policy before such mandates are expanded and linked to primary school entry, for example, or adopted by other countries. The parameters could include, but are not limited to those described in Box 2.

Equity and justice

“No Jab No Pay” raises significant questions of equity because of the differential way in which the penalties are dispersed. Vaccine objectors with higher SES are

not equally penalised because two of the payments are income tested. There is a greater effect on families living in poverty or migrant and refugee families.

Equity of access to child care is also affected through it being made less affordable for some families affected by the removal of rebates and benefits. In 2008, the Commonwealth and the States and Territories signed a National Partnership Agreement to ensure that all children have access to early childhood education.

Strategies in which services can be strengthened to improve access among the motivated are more just and bring larger gains. They may include home visiting services and reminder systems, enhanced provider support systems, improved timely entry of the child onto the Australian Immunisation Register and ongoing free vaccine to children over 10, to name a few.

Hence, penalties for vaccine rejection is neither the most effective nor fair way to improve vaccination rates when it brings significant social and economic risks for the most vulnerable. Penalties also compound the disadvantage for children already more vulnerable to vaccine-preventable diseases – effectively punishing them for the decision of their parents.

Autonomy

A high level of financial coercion reduces autonomy and undermines valid consent. Coercion is justified only when no other options are unavailable. It is better to employ the least restrictive option with the greatest gain.²⁵ The loss of autonomy in vaccination is particularly problematic for those at the margins of vaccine acceptance (the highly hesitant parents as opposed to the refusers) who value their agency in their parental decision making, which this policy is challenging.

Reciprocity

Reciprocity means there is a mutual exchange and fair play. If parents are obliged by government to vaccinate their children and face not just benefits, but possible risks of rare serious side effects, it is beholden on government to reciprocate. Yet the No Jab, No Pay amendment bill has been implemented without a no-fault vaccine injury compensation system, although 19 other countries have done so.²⁶ We strongly recommend that such a scheme is introduced.

Trust

Sustaining public trust is vital as the incidence of VPDs declines and the risk/benefit margins for vaccination narrow. These strong penalties diminish trust in the healthcare system because they bring financial hardship and limited access to early childhood education, contradicting the goals of vaccination - the health and wellbeing of children and society. The discord between the means and ends engenders more alienation from a healthcare system that vaccine rejecting and hesitant parents already struggle to trust.

Moreover, trust-erosion means vaccine safety scares can more readily take seed in a soil of hostility towards government, expert systems and their interface – the clinician.^{27, 28} This environment can invigorate the anti-vaccination lobby, perpetually ready to draw new recruits from the ranks of the disenfranchised. Indeed, compulsory smallpox vaccination in the 19th century in Britain and the United States connected anti-vaccination leagues with rights-based campaigners who may have otherwise ignored the vaccination issue.²⁹ As such, ‘conscientious’ objection to compulsory vaccination was introduced in Britain in 1898. Today there are many active and vocal anti-vaccination activists around the world seeking to increase their impact, membership fees, and/or product sales. Although the more radical groups have traditionally been sidelined in Australia,

“No Jab No Pay” may galvanise others with lobbying experience, repeating the pattern of over 100 years ago where concerns about personal freedoms could become a more salient way to perpetuate misinformation about vaccination.

Conclusions

While vaccination is well supported by evidence, the current “No Jab No Pay” legislation is not and brings a series of unintended negative consequences. It is essential to be clear who this Bill targets and consequently who it affects. If the main intention of the Bill is to mandate that vaccine rejecting families accept their public responsibility to protect their child(ren) and others, then the level of severity appears disproportionate. However, if the policy is primarily meant to target those in the access gap – the 6.2% described above, then increased frequency and age expansion of the penalty could be retained, whilst retaining conscientious objection and allowing a hard-to-obtain exemption to provide a pressure valve for steadfast vaccine objectors.

We acknowledge that vaccine rejection is a perennial problem for vaccine programs, particularly since it clusters in some communities. More evidence is needed to address it. Meanwhile, we recommend:

- Retention of the requirement to register vaccination objection as an exemption to family assistance payments and child care entry. Yearly registration with a doctor or vaccination provider until the child turns 5 years would make vaccination objection inconvenient. Evidence shows that difficult-to-acquire exemptions are associated with less exemption. It would also encourage engagement with the health system and provide opportunities for parents to re-visit their decision where some will eventually decide to vaccinate⁴;

- Enforcing state-based exclusion rules for un-vaccinated children from child care or school during an outbreak;
- Implementing universal record checks for full vaccination or exemptions in child care, primary school and with the addition of high school, where under vaccinated adolescents are often missed;³⁰
- Comprehensive support for health professionals in the use of communication approaches and resources to be used with vaccine-hesitant and rejecting parents;
- Provision of more structured support for clinicians when parents request a non-valid medical exemption;
- Medical exemptions should remain specific to true contraindications to vaccination, although additional exemptions may need to be considered in more extreme cases, such as, where a child cannot be vaccinated unless they receive a general anaesthetic (see Box 1);
- Investigating more collaborative approaches to working with communities with higher rates of vaccine rejectors and the professionals who influence them. For example, a peer-to-peer educator program was implemented in Washington State <http://www.vaxnorthwest.org/approach>;
- Introduction of a no-fault compensation scheme for rare but serious vaccine injury.

In conclusion, an evidence-based approach to under-vaccination involves comprehensive, multifactorial approaches. Regulatory approaches to vaccine rejection should be firm but fair, enabling hard-to-reach exemptions that promote engagement, not alienation from the health system.

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Table 1

Potential impacts of the Australian Government's "No Jab, No Pay" Bill on the three major groups that comprise under-vaccinated children on the Australian Childhood Immunisation Register.

Three groups of children not up to date on ACIR (8% of all children in December 2015)	Area of policy change and potential impacts		
	Removal of conscientious objection exemption	Increased frequency of existing penalty - from ages 1, 2 and 5 years to every year*	Extension of existing penalties to age 19 years
Group 1 <i>Children not up to date where a vaccine objection is recorded.</i>	Fully vaccinate or; Continue to not vaccinate and lose payments or; Obtain a valid exemption and payments continue#.	Fully vaccinate or; Continue to not vaccinate and lose payments yearly or; Obtain a valid exemption and payments continue.	Child catches-up on vaccines that were due by 5 years or; Child does not catch-up and parents do not receive payments for which they were previously eligible. Obtain a valid exemption and payments continue.
Group 2 <i>Children not up to date and where a vaccine objection is not recorded.</i>	No impact from this aspect of the policy. These children were not meeting previous requirements and are not affected by removal of an objection provision.	Communication from Department of Social Services warning of potential loss of payment may prompt catch-up or; Child remains under-vaccinated and now each year parents do not receive payments or; Child remains under-vaccinated and parents unaffected due to not being previously eligible for payments. Obtain a valid exemption and receive payments.	Child catches-up on vaccines that were due by 5 years or; Child does not catch-up and parents no longer receive payments each year until child turns 20 years or; Child does not catch-up but parents unaffected due to not being eligible for payments. Obtain a valid exemption and receive payments.
Group 3 <i>Up-to-date children incorrectly recorded</i>	No impact.	Error on ACIR may be corrected or;	Error corrected through retrieval of records or child being

as not up-to-date on ACIR.		Error not corrected and yearly loss of payments despite child being fully vaccinated or; Error not corrected but no penalty due to previous non-eligibly for payments.	re-vaccinated; Error not corrected and penalty experienced yearly until child turns 20 years or; Error not corrected but no penalty due to previous non-eligibility for payments.
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* Prior to 2016, ineligibility for payments applied when the child turned 1, 2 and 5 years and was assessed as not being up-to-date for age milestone. The No Jab No Pay amendment bill (2015) applies this penalty each financial year if the child does not meet the requirements.

From 2016, valid exemptions are: a medical contraindication, natural immunity to a disease, being in a vaccine study, temporary unavailability of vaccine, child vaccinated overseas, or a decision at the discretion of the Secretary. "Conscientious objection" is no longer a valid exemption.

Box 1

Composite case studies of Australian families seeking medical exemptions for non-eligible children under current No Jab No Pay requirements.*

Case 1: Autism in sibling and fear regarding vaccinating subsequent children with the MMR vaccine.

A family with a 5 year old boy with non-verbal autism are too afraid to vaccinate their next child with the MMR vaccine. No amount of discussion regarding the facts or evidence can persuade them that there is no link between MMR and autism - their first child regressed developmentally within 1 month of the MMR vaccine and he did not get the second MMR vaccine or any further vaccines. Serology showed that he was not immune to measles and needs a second dose. Their younger child can't get into 3 year old child care because he is not up-to-date with his vaccines and the family can't receive the relevant payments. The parents have decided to move interstate to get him into child care but this means moving away from family supports and the father is concerned about finding further factory work. The other option is for the family to stay in Victoria but the mother will have to give up her job to care for the 3 year old. This will mean substantial financial hardship for the family as there will only be one full-time salary.

Case 2: Child who has experienced a significant adverse event following immunisation (AEFI)

A family with a 6 month old baby boy are too afraid to give any further vaccines due to a suspected AEFI after his 4 month vaccines. After his 4 month vaccines he became quiet, less communicative and appeared to lose some skills, such as rolling for a 4 to 6 week period. He has only just fully recovered and come "back to normal". The family cannot be persuaded to continue to vaccinate and will lose all financial assistance payments and will not be able to enroll him into child care. His mother needs to go back to work to further support him and his three sublings.

Case 3: Secondary school child with a developmental disability

A family with a 13 year old autistic boy, who is 80 kg and very aggressive to his parents and staff at school, are unable to get their son vaccinated and he is not up-to-date with his MMR and hepatitis B vaccines, which are linked to family assistance payments. The parents have unsuccessfully tried sedation in the day medical unit twice at the hospital. During the second attempt the mother was injured by her son whilst trying to hold him down to get the vaccines. She is upset by both previous hospital attempts and her son is traumatised and won't go into the hospital now. The family cannot justify a general anaesthetic for him to receive his vaccines. They will now lose the

FTB-A (supplement) and the mother reports having to get a full-time job to increase the family income; the father has taken an extra weekend job.

***Case studies do not represent actual cases but are composites based on clinical experience.**

Box 2

Suggested parameters needed for evaluation of penalty-based policies.

Evaluation of health impacts including:
• Ascertainment of vaccination status of children previously affected by vaccination objection; • Changes in patterns of vaccine-preventable disease (VPD) outbreaks in formal and informal childcare arrangements; • Changes in rates of medical exemptions;
Evaluation of the social and economic consequences of the federal and state legislation including:
• Consistency of implementation and enforcement of child care regulations; • Impact on non-compliant families – movement to other states, movement overseas, workforce participation, other impacts of financial hardship; • Audits of accuracy of the Australian Immunisation Register to determine percentage of children likely to be penalised incorrectly; • Changes in community attitudes and trust in vaccination programs; • Relationships with health care providers and social security services; • Reports of related aggression during health care encounters